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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,150	12/26/2001	Luc Desnoyers	P3030R1C9	4456

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT PAPER NUMBER

1649

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

10/036,150

Applicant(s)

DESNOYERS ET AL.

Examiner

Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-30, 32-35 and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-27, 30, 35 and 38-41 is/are rejected.
- 7) ☒ Claim(s) 28, 29 and 32-34 is/are objected to.
- 8) ☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/27/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/27/05 has been entered.
2. In view of the papers filed 6/27/05, the inventorship in this nonprovisional application has been changed by the deletion of Eaton, Pan, Stewart, Watanabe and Zhang.
3. Applicant's arguments filed 6/27/05 have been fully considered but they are not deemed to be persuasive.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claims 28, 29 & 32-34 stand objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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6. Claims 22-27, 30 & 35-41 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper No: 20050321, and as follows.

In contrast to Applicants' arguments on pages 8-9 of the response, the mere statement on page 28 of the specification that "[t]he transmembrane domain has been *tentatively* identified as extending from about...", and that this "*may* be a type II transmembrane domain" [emphasis added] is inconsistent with Figure 20 specifically disclosing that N-myristoylation sites exist at 6 different positions between amino acids 77-310, which therefore, are *intracellular* versus extracellular because these are the putative sites where the scr protein binds to the cytoplasmic face of the plasma membrane. In other words, it remains unknown and not disclosed what amino acid residues are located within the "extracellular domain", if any such domain even exists, because nowhere in the specification is it specifically stated what portion of the PRO4405 polypeptide is "extracellular". Therefore, as previously made of record, redefining the extracellular domain as amino acids 77-310 after-the-fact still constitutes new matter.

7. Claims 22-27, 30, 35 & 38-41 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

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claimed invention, for the reasons made of record in Paper No: 20040902 & 20050321, and as follows.

In contrast to Applicants' assertions on pages 9-13 of the response, page 71 of the specification specifically states that "[t]he [encoded] PRO polypeptides described herein *may be isolated from a variety of sources*, such as from human tissue types *or from another source...* [emphasis added]". In contrast, the claims fail to recite that the claimed nucleic acids are "an isolated **human** nucleic acid...". No written description is provided in the specification for any other species of PRO4405 molecules, in which disclosure of a single "human" polynucleotide sequence does not reasonably constitute "the claimed genus of polynucleotides". Thus, in contrast to Applicants' assertions, the courts holdings in *Vas-Cath*, *Fiers v. Revel*, *Univ. California v. Eli Lilly and Co.*, and especially *Fiddes v. Baird* are reasonably applicable. Applicants then refer to Example 14 from the training materials for the written description guidelines. In contrast to Applicants' assertions, the claims do not define an open reading frame in a definable nucleic acid molecule (e.g., as it relates to base claim 22c or 35, etc), but instead encompasses undescribed nucleotide sequences. The specification further fails to establish any disclosed correlation between function and structure, or by a combination of such identifying characteristics, for the claimed encoded PRO 4405 polypeptides, or establish any correlation with any other encoded polypeptide known within the art with similar function, such as "catalyzing the reaction of $A > B$ ". Lastly, claims 22-24 are distinguished from Example 14 in that these claims are not limited to a "nucleic acid having at least 95% nucleic acid sequence identity... encoding [a] polypeptide", similar to that illustrated in Example 14, in which a reasonable correlation between structure and function may be possible for such a "claimed genus

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of polynucleotides”. Thus, Applicants’ arguments are not persuasive for the reasons made of record.

8. Claim 35 is rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al. (clone EST70856; Accession no. AA361388; April 21, 1997), for the reasons previously made of record in Paper No: 20040902.

Adams et al. teach an isolated human 5' cDNA clone, whose sequence is deposited with the GenBank/EMBL database, which “comprises” a nucleic acid that is 98% identical to nucleotide residues 144 to 397 of SEQ ID NO: 44, and therefore, clearly will hybridize to SEQ ID NO: 44 under stringent conditions at all identical nucleotide residues. It is further noted that Adams’ clone is missing about 2/3rds of the signal peptide encoding sequence, contains the N-myristoylation sites at residue #s 52-58, 100-106 & 125-131, the glycosylation site at 56-60, and the transmembrane site at 58-76; thereby, containing sufficient structure, similar to that claimed, to inherently possess the recited functional language of inducing chondrocyte redifferentiation; absent evidence to the contrary.

It is also noted that Adams’ clone is cloned in the vector pBluescript SK, and transfected into *E. coli* host cells for this “clone” “in host 165712”.

Lastly, as previously made of record, the above rejection is based in part upon a disclosure provided in a computer database record. Because the database was indexed so as to be available to the relevant part of the public, it is considered to be a U.S.C. § 102; see *In re Wyer*, 210 USPQ 790.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert C. Hayes, Ph.D.
September 6, 2005

 **ROBERT C. HAYES, PH.D.**
Primary PATENT EXAMINER